



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifiers CMS-116 and CMS-10225]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**

ADDRESSES: When commenting, please reference the document identifier or OMB control number (OCN). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. Electronically. You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. By regular mail. You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: Document Identifier/OMB Control Number \_\_\_\_\_

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at

<http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT:

Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see ADDRESSES).

CMS-116 Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations

CMS-10225 Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

#### Information Collections

1. Type of Information Collection Request: Revision of a currently approved collection; Title of Information Collection: Clinical Laboratory Improvement Amendments (CLIA) Application Form and Supporting Regulations; Use: The application must be completed by entities performing laboratory's testing specimens for diagnostic or treatment purposes. This information is vital to the certification process. Form Number: CMS-116 (OCN#: 0938-0581); Frequency: Biennially and Occasionally; Affected Public: Private sector- Business or other for-

profits and Not-for-profit institutions; Number of Respondents: 242,000; Total Annual Responses: 34,200; Total Annual Hours: 25,650. (For policy questions regarding this collection contact Sheila Ward at 410-786-3115.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Disclosures Required of Certain Hospitals and Critical Access Hospitals Regarding Physician Ownership; Use: There is no Medicare prohibition against physician investment in a hospital or critical access hospitals (CAH). Likewise, there is no Medicare requirement that a hospital or CAH have a physician on-site at all times, although there is a requirement that they be able to provide basic elements of emergency care to their patients. Medicare quality and safety standards are designed to provide a national framework that is sufficiently flexible to apply simultaneously to hospitals of varying sizes, offering varying ranges of services in differing settings across the nation. At the same time, however, patients might consider an ownership interest by their referring physician, the presence of a physician on-site or both to be important factors in their decisions about where to seek hospital care. A well-educated consumer is essential to improving the quality and efficiency of the healthcare system. Accordingly, patients should be made aware of the physician ownership of a hospital, whether or not a physician is present in the hospital at all times, and the hospital's plans to address patients' emergency medical conditions when a physician is not present. The intent of the disclosures is to increase the transparency of the hospital's ownership and operations to patients as they make decisions about receiving care at the hospital. Form Number: CMS-10225 (OCN: 0938-1034); Frequency: Occasionally; Affected Public: Private sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 265; Total Annual Responses: 57,387,927; Total Annual Hours: 1,265,116. (For policy questions regarding this collection contact Teresa Walden

at 410-786-3755).

Dated: December 9, 2013. \_\_\_\_\_

Martique Jones,

Deputy Director, Regulations Development Group,

Office of Strategic Operations and Regulatory Affairs.

Billing Code: 4120-01-U-P

[FR Doc. 2013-29725 Filed 12/12/2013 at 8:45 am; Publication Date: 12/13/2013]